Exhibit 300: Capital Asset Summary

Part I: Summary Information And Justification (All Capital Assets)

Section A: Overview & Summary Information

Date Investment First Submitted: 2009-06-30
Date of Last Change to Activities: 2012-07-23
Investment Auto Submission Date: 2012-02-23
Date of Last Investment Detail Update: 2012-02-23
Date of Last Exhibit 300A Update: 2012-07-23
Date of Last Revision: 2012-07-23

Agency: 009 - Department of Health and Human Services **Bureau:** 10 - Food and Drug Administration

Investment Part Code: 01

Investment Category: 00 - Agency Investments

1. Name of this Investment: FDA CDER Automated Drug Information Management System

2. Unique Investment Identifier (UII): 009-000005345

Section B: Investment Detail

1. **Provide a brief summary of the investment, including a brief description of the related benefit to the mission delivery and management support areas, and the primary beneficiary(ies) of the investment. Include an explanation of any dependencies between this investment and other investments.**

The Automated Drug Information Management System (ADIMS) is being developed as an integrated, fully electronic information management system for the receipt, validation, evaluation, reporting, and dissemination of drug application, safety and efficacy data. As the core enterprise architecture for FDA's pre-market drug review process, ADIMS aims to integrate or replace all relevant systems. The system will seamlessly unify multiple applications into one application which will include single sign-on access to information and tools used in daily decision-making. The Document Archiving, Reporting, and Regulatory Tracking System (DARRTS) will be the backbone of the system. Over fifty large and small systems will be integrated into ADIMS, including the Corporate Oracle Management Information System (COMIS), the Electronic Document Room (EDR), and the Division File System (DFS). As the volume of technologically advanced electronic information coming into FDA escalates, the need for a robust information management system becomes more critical. In addition to facilitating the drug review and approval process, this integrated data management system will collect and evaluate electronic clinical data and facilitate the identification of trends and other important drug regulatory review information (e.g., potential product safety issues). Also, the validation and back-up capabilities of ADIMS will facilitate data verification and correction with increased efficiency. Consolidating current stovepipe and stand-alone drug information systems into a cohesive, easily supportable platform will give

reviewers the ability to access information from a single interface, thus reducing redundancy. This will improve data quality and performance objectives, as well as reduce time and resources required to keep multiple systems updated. As a result, ADIMS will directly support the e-Government initiative by creating efficient, electronic access to current and complete information within the Agency. ADIMS also supports the HHS strategic goal to improve health care quality, safety, cost and value by allowing real-time transfer of information. In addition to this, the capability to accept electronic submissions will improve the FDA's responsiveness to consumers, industry, and healthcare providers.

2. **How does this investment close in part or in whole any identified performance gap in support of the mission delivery and management support areas? Include an assessment of the program impact if this investment isn't fully funded.**

ADIMS directly supports the goal of e-Government by creating consolidated and efficient electronic access to the most up-to-date and complete information within the Agency. This, along with the system's capabilities of accepting electronic submissions and facilitating real-time transfer of information, improves the FDA's responsiveness to the American public, consumers, industry, and healthcare providers. Provides enhanced communications and data flow in support of the regulatory review and safety processes. This is accomplished through a unified set of systems that enable access to information and tools used in daily decision-making by drug review and safety evaluation teams. Further consolidates the receipt, tracking, management, and reporting of information about clinical investigation and market submissions for human drugs and therapeutics biologics. Absorbs and better manages the submission and tracking of Establishment Evaluation Requests as part of the ADIMS support of the drug application review process. Now incorporates relevant Substance and Ingredient information. Focused reporting project will provide consistent and prompt reports to the user community, Congress, FOIA, and the health care industry. Reporting is approximately 40% of the end-user experience and this will now be accomplished through a common interface system. Eliminates redundant systems, and consolidates and migrates functionality and maintenance into a smaller set of systems; while at the same time providing legacy tasks with enhanced capabilities. Provides upgrades of technology in both hardware and software to meet the growing demand of functionality and performance from business. Provides the platform for continued program expansion, such as the expanded automation of support tracking processes for drug product and therapeutic biologic product review; as well as drug safety issues. Meets performance goals of PDUFA. It is critical that the ADIMS Investment continues to maintain and enhance existing systems, consolidate functionality, as well as invest in new capabilities to further meet growing business needs and new legislative or regulatory requirements.

3. **Provide a list of this investment's accomplishments in the prior year (PY), including projects or useful components/project segments completed, new functionality added, or operational efficiency achieved.**

Initiated a Technical Refresh and completed phase I of the Technical Refresh. Completed Planned DME Releases 3.2 and 3.3 along with multiple O&M Releases to maintain stability of the Investment components. Completed a significant change in the management of the Investment and strategic planning. LX continued to deploy regularly scheduled O&M releases. EES continued to deploy regularly scheduled O&M releases. eCTD continued to deploy regularly scheduled O&M releases. EDR/ASR continued to deploy regularly scheduled

O&M releases. SRS/ID also continued to deploy regularly scheduled O&M releases.

4. **Provide a list of planned accomplishments for current year (CY) and budget year (BY).**

FY12 DARRTS O&M releases to address defects. FY12 DARRTS DME Release 3.4. FY12 DARRTS Technical Update Phase II. FY12 DRBI O&M releases to address defects. FY12 DRBI DME Release 3.4. FY12 SRS/ID O&M releases to address defects. FY12 EDR/ASR O&M releases to address defects. FY12 LX O&M releases to address defects. FY12 EES O&M releases to address defects. FY12 eCTD O&M releases to address defects. FY12 DARRTS DME Release 3.5. FY12 DRBI DME Release 3.5. FY13 DARRTS O&M releases to address defects. FY13 DARRTS DME. FY13 DRBI O&M releases to address defects. FY13 DRBI DME. FY13 SRS/ID O&M releases to address defects. FY13 EDR/ASR O&M releases to address defects. FY13 LX O&M releases to address defects. FY13 EES O&M releases to address defects. FY13 eCTD O&M releases to address defects. FY13 DARRTS: DME - Technical Refresh Phase III will be prolonged due to budget cut. FY13 DARRTS: O&M - Some of the defects will be deferred to future releases in FY14.

5. **Provide the date of the Charter establishing the required Integrated Program Team (IPT) for this investment. An IPT must always include, but is not limited to: a qualified fully-dedicated IT program manager, a contract specialist, an information technology specialist, a security specialist and a business process owner before OMB will approve this program investment budget. IT Program Manager, Business Process Owner and Contract Specialist must be Government Employees.**

2011-07-21

Section C: Summary of Funding (Budget Authority for Capital Assets)

1.

Table I.C.1 Summary of Funding

	PY-1 & Prior	PY 2011	CY 2012	BY 2013
Planning Costs:	$2.9	$0.0	$0.0	$0.0
DME (Excluding Planning) Costs:	$18.1	$6.0	$9.7	$8.8
DME (Including Planning) Govt. FTEs:	$0.0	$0.5	$0.5	$0.5
Sub-Total DME (Including Govt. FTE):	$21.0	$6.5	$10.2	$9.3
O & M Costs:	$9.4	$10.0	$11.1	$10.6
O & M Govt. FTEs:	$3.2	$0.5	$0.4	$0.4
Sub-Total O & M Costs (Including Govt. FTE):	$12.6	$10.5	$11.5	$11.0
Total Cost (Including Govt. FTE):	$33.6	$17.0	$21.7	$20.3
Total Govt. FTE costs:	$3.2	$1.0	$0.9	$0.9
# of FTE rep by costs:	24	8	7	7
Total change from prior year final President's Budget ($)		$-1.8	$0.9	
Total change from prior year final President's Budget (%)		-9.43%	4.29%	

2. If the funding levels have changed from the FY 2012 President's Budget request for PY or CY, briefly explain those changes:

The consolidation of legacy and stand alone systems into a more centralized investment has lead to steady state cost savings. Multiple systems have been, and continue to be, integrated into the ADIMS Investment either through interface development or migration of functionality into DARRTS. Consolidating current stovepipe and stand-alone systems into a cohesive, easily supportable platform has freed resources and lessened dependence on external support for maintenance and upgrades.

Section D: Acquisition/Contract Strategy (All Capital Assets)

Table I.D.1 Contracts and Acquisition Strategy

Contract Type	EVM Required	Contracting Agency ID	Procurement Instrument Identifier (PIID)	Indefinite Delivery Vehicle (IDV) Reference ID	IDV Agency ID	Solicitation ID	Ultimate Contract Value ($M)	Type	PBSA ?	Effective Date	Actual or Expected End Date
Awarded		GST0007AJ0007									
Awarded		GS-35F-0152N									
Awarded		GSTFMGBPA090017									

2. If earned value is not required or will not be a contract requirement for any of the contracts or task orders above, explain why:

Exhibit 300B: Performance Measurement Report

Section A: General Information

Date of Last Change to Activities: 2012-07-23

Section B: Project Execution Data

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
283741	Document Archiving, Reporting & Regulatory Tracking System	DARRTS is the principal CDER system that supports the receipt, tracking, management, and reporting of information about clinical investigation and market submissions for human drugs and therapeutics biologics. Each major release of DARRTS integrates legacy systems and progressively improves the FDA's ability to provide reports to Congress on a number of issues, including meeting performance goals related to the Prescription Drug User Fee Act (PDUFA). DARRTS also includes support for regulatory reporting capabilities using Business Objects. There are Business Objects universes that support over two hundred "canned" reports for the LX and DARRTS systems. The reporting component also provides ad-hoc reporting capabilities. These reports provide information to the user community, Congress, FOIA			

Table II.B.1 Projects

Project ID	Project Name	Project Description	Project Start Date	Project Completion Date	Project Lifecycle Cost ($M)
		requests, drug formulations, marketing and advertising information, and other associated requests.			

Activity Summary

Roll-up of Information Provided in Lowest Level Child Activities

Project ID	Name	Total Cost of Project Activities ($M)	End Point Schedule Variance (in days)	End Point Schedule Variance (%)	Cost Variance ($M)	Cost Variance (%)	Total Planned Cost ($M)	Count of Activities
283741	Document Archiving, Reporting & Regulatory Tracking System							

Key Deliverables

Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
283741	283741: DARRTS 1-1x TBP INDS's and Safety Issues	TBP INDs and Safety Issues, Document Room data entry functions for incoming supporting documents, Reviewer/RPM/Executive check-in and signoff of internally generated documents (communications), Review Teams and Assignments, Goal Tracking, Searching and Reports. Introduced support for new dossier type - Safety Issue, Full-text search of all communication content, Track a	2007-01-31	2007-01-31	2007-01-31	791	0	0.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
		single incoming supporting Document across multiple applications,						
283741	283741: DARRTS 2 - 2x, Drug IND's Master Files, EUA's New Application Notification	Drug INDs, Master files, EUAs, New Application Notification, Personal lists for signers and cc recipients, Add references between communications. Quick NAI (No Action Indicated) for reviewers, Work plans for Safety Issues with Date Calculator, DARRTS query availability opened up for all FDA staff, Integrated Gateway Receipt Information,	2008-09-30	2008-09-30	2008-09-30	729	0	0.00%
283741	283741: DARRTS 3-3.2	combined/eliminated the following: COMIS (NDE MIS, ANDA MIS, ECH2 OND, ECH2 OGD, Comments, BSTS, GSS), PMC, DFS, Pediatric Page, IMTS, ANDA Data Warehouse, Bioequivalence Study Tracking, CMC TRACK, OGD Master Queue	2011-05-15	2011-05-15	2011-05-15	229	0	0.00%
283741	283741: Release Planning -Finalize SSO Specifications	Finalize SSO component specificaitons	2011-07-15	2011-07-15	2011-07-15	30	0	0.00%
283741	283741: Business Requirements -Sign off	Signed off on Buisness Requirements	2011-07-27	2011-07-27	2011-07-27	26	0	0.00%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
283741	283741: Design - System Design Document	System Design Document	2011-08-08	2011-08-08	2011-08-08	19	0	0.00%
283741	283741: Development complete, Integrated code unit tested	Development complete, Integrated code unit tested, code peer reviewed. Peer Review of functionality completed in Development	2011-08-22	2011-08-22	2011-08-22	21	0	0.00%
283741	283741: Testing and Tranining -Completed Training Materials and Testing	Completed Training Materials, Completed System Test with accepted Test Report, Completed user acceptance test with accepted use acceptance report, Prepare VDD for system test, preprod, production	2011-09-15	2011-09-15	2011-09-15	23	0	0.00%
283741	283741: Release Planning -Baseline URD and walkthrough	Baseline URD and detailed walk-through	2011-09-16	2011-09-20	2011-09-20	15	-4	-26.67%
283741	283741: Release Planning -Baseline URD and walkthrough	Baseline URD and detailed walk-through	2011-09-20	2011-09-20	2011-09-20	19	0	0.00%
283741	283741: Implementation -Validate Prepared VDD for pre-production deployment	Validate Prepared VDD for pre-production deployment, Release Transition activities, rollover activities to pre-production and production	2011-09-30	2011-09-22	2011-09-22	14	8	57.14%
283741	283741: Business Requirements -Signed off	Signed off on Business Requirements	2011-10-07	2012-01-17	2012-01-17	25	-102	-408.00%
283741	283741: Business Requirements -Signed off	Signed off on Business Requirements	2011-10-14	2012-01-17	2012-01-17	32	-95	-296.88%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
283741	283741: Design -System Design Document	System Design Document	2011-10-18	2011-10-28	2011-10-28	29	-10	-34.48%
283741	283741: Development - Development Complete, integrated code tested	Development complete, Integrated code unit tested, code peer reviewed. Peer Review of functionality completed in Development	2011-10-27	2012-03-15	2012-01-18	24	-83	-345.83%
283741	283741: Design - System Design Document	System Design Document	2011-10-28	2011-10-28	2011-10-28	32	0	0.00%
283741	283741: Testing and Training -Complete Training Materials, System Test	Completed Training Materials, Completed System Test with accepted Test Report, Completed user acceptance test with accepted use acceptance report, Prepare VDD for system test, preprod, production	2011-12-06	2012-01-31	2012-01-31	42	-56	-133.33%
283741	283741: Implementation -Validate VDD for pre-production	Validate Prepared VDD for pre-production deployment, Release Transition activities, rollover activities to pre-production	2011-12-09	2012-04-12	2012-02-13	3	-66	-2,200.00%
283741	283741: Release Planning -Baseline URD and walkthrough	Finalize Technical Upgrade component specificaitons	2011-12-15	2012-04-02	2011-12-15	73	0	0.00%
283741	283741: Development -Development Complete, integrated code tested	Development complete, Integrated code unit tested, code peer reviewed. Peer Review of functionality completed in Development	2012-03-15	2012-03-15	2012-01-18	136	57	41.91%

Key Deliverables								
Project Name	Activity Name	Description	Planned Completion Date	Projected Completion Date	Actual Completion Date	Duration (in days)	Schedule Variance (in days)	Schedule Variance (%)
283741	283741: Business Requirements -Signed off	Signed off on Business Requirements	2012-04-02	2012-05-25	2012-05-21	82	-49	-59.76%
283741	283741: Testing and Training -Complete Training Materials, System Test	Completed Training Materials, Completed System Test with accepted Test Report, Completed user acceptance test with accepted use acceptance report, Prepare VDD for system test, preprod, production	2012-04-05	2012-01-31	2012-01-31	108	65	60.19%
283741	283741: Implementation -Validate VDD for pre-production	Validate Prepared VDD for pre-production and production deployment, Release Transition activities, rollover activities to pre-production and production	2012-04-27	2012-04-12	2012-02-13	21	74	352.38%
283741	283741: Design - System Design Document	System Design Document	2012-06-01	2012-06-22	2012-06-22	59	-21	-35.59%

Section C: Operational Data

Table II.C.1 Performance Metrics

Metric Description	Unit of Measure	FEA Performance Measurement Category Mapping	Measurement Condition	Baseline	Target for PY	Actual for PY	Target for CY	Reporting Frequency
Number of defects of fixed	#	Technology - Reliability and Availability	Under target	123.000000	123.000000	123.000000	150.000000	Monthly
Incerase number of applications using SSO	#	Technology - Efficiency	Over target	1.000000	1.000000	1.000000	3.000000	Semi-Annual
Increase number of BLA Communications	#	Mission and Business Results - Services for Citizens	Over target	0.000000	0.000000	0.000000	200.000000	Semi-Annual
Reduce time for contractor to contact client on TroubleTickets	hours	Customer Results - Timeliness and Responsiveness	Under target	3.000000	3.000000	3.000000	2.000000	Monthly
Increase number of Business Data refreshes in PreProd	#	Customer Results - Service Quality	Over target	2.000000	2.000000	2.000000	4.000000	Quarterly
Maintain SLA response times for resolution of severity 2 trouble tickets	hours	Technology - Efficiency	Under target	8.000000	8.000000	8.000000	8.000000	Monthly